ARC 1030C

PHARMACY BOARD[657]

Adopted and Filed Emergency After Notice

Pursuant to the authority of Iowa Code section 147.76 and 2013 Iowa Acts, Senate File 353, the Board of Pharmacy hereby amends Chapter 8, "Universal Practice Standards," Iowa Administrative Code.

The amendment rescinds current rule 657—8.33(147,155A) and adopts new rule 657—8.33(155A). The rule establishes training and continuing education requirements for pharmacists engaged in the administration of vaccines, identifies the vaccines that a qualified pharmacist may administer to patients within specified age categories, and requires compliance with and utilization of the United States Centers for Disease Control and Prevention's (CDC) protocol for the administration of vaccines.

The rule also requires the pharmacist, prior to administering a vaccine on the approved adult vaccination schedule of the CDC Advisory Committee on Immunization Practices, a vaccine recommended by the CDC for international travel, or a vaccine to be administered pursuant to a prescription or medication order for an individual patient, to consult with the statewide immunization registration or health information network. The rule requires the pharmacist to report the administration of a vaccine described in this paragraph to the statewide immunization registry or health information network and to the patient's primary health care provider, if known, within 30 days of the administration.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the July 24, 2013, Iowa Administrative Bulletin as **ARC 0883C**. The Board received numerous written comments regarding the proposed rule. The adopted rule differs from that published under Notice.

Many of the commenters expressed concerns that pharmacists would be required to check the statewide immunization registration prior to administration pursuant to protocol of an influenza vaccine. Others were concerned that pharmacists would be required to report the administration pursuant to protocol of every influenza vaccine to the statewide immunization registry and to the patient's primary health care provider. Neither of these perceived requirements, as they relate to influenza vaccines administered via protocol, is included in the noticed or adopted rule. Subrule 8.33(7) has been amended to clearly state the exemption from these requirements for influenza vaccines and other emergency vaccines administered pursuant to protocol.

Other suggestions included eliminating the duplicative phrases "or immunization" and "and immunization" throughout the rule, authorizing the signing of a protocol between one or more authorized pharmacists and one or more licensed prescribers practicing in Iowa, eliminating the requirement that the prescribers be practicing within the local provider service area, and eliminating paragraph 8.33(5)"c" since the vaccinations identified in the paragraph would be included in paragraph 8.33(5)"a." These suggested changes have been made to the proposed rule by eliminating paragraph 8.33(5)"c" as duplicative and amending paragraph 8.33(3)"a" to require that a protocol be signed by a prescriber practicing in Iowa. Since the definitions of "immunization" and "vaccine" are identical, the duplicative phrases identifying both terms have been amended throughout the rule to address only "vaccine" or "vaccines."

Based on a suggestion from a commenter, the definition of "vaccine" has been amended to read as follows: "*'Vaccine'* means a specially prepared antigen administered to a person for the purpose of providing immunity." In addition, subparagraph 8.33(2)"a"(2), numbered paragraph "8," has been amended to add the identification of contraindications to the vaccine as a subject to be addressed by the education requirements for an authorized pharmacist.

The requirements for a protocol have been amended in subrule 8.33(3) to require that a protocol be unique to a pharmacy and identify the pharmacists authorized to administer vaccines pursuant to the protocol and that serious complications be reported to the prescriber who signed the protocol and to the Vaccine Advisory Event Reporting System (VAERS). Reporting to VAERS has also been added to subrule 8.33(6) for vaccines administered via prescription.

Commenters expressed support for the requirements for pharmacist continuing education relating to the administration of vaccines and generally supported the amendment and the expanded opportunity for pharmacists to contribute to increased immunization rates and patient health and safety in Iowa.

The Board finds, pursuant to Iowa Code section 17A.5(2)"b"(2), that the emergency adoption of this rule confers a benefit on the public. Pharmacists are currently in the process of establishing protocols for the administration of the annual influenza vaccines. Delaying the effective date of this rule to a normal effective date under the rule-making process will delay availability of influenza vaccine administration by pharmacists, increasing the risk of infection to patients in Iowa. Pharmacists in Iowa routinely administer the majority of influenza vaccines prior to and during the annual flu season.

The amendment was approved during the August 28, 2013, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code sections 155A.3 and 155A.4 and 2013 Iowa Acts, Senate File 353.

This amendment became effective on September 1, 2013.

The following amendment is adopted.

Rescind rule 657—8.33(147,155A) and adopt the following **new** rule in lieu thereof:

657—8.33(155A) Vaccine administration by pharmacists. An authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule.

8.33(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACIP" means the CDC Advisory Committee on Immunization Practices.

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has met the requirements identified in subrule 8.33(2).

"CDC" means the United States Centers for Disease Control and Prevention.

"Immunization" shall have the same meaning as, and shall be interchangeable with, the term "vaccine."

"Protocol" means a standing order for a vaccine to be administered by an authorized pharmacist.

"Vaccine" means a specially prepared antigen administered to a person for the purpose of providing immunity.

8.33(2) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of the requirements in paragraph 8.33(2)*"a"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 8.33(2)*"b."*

a. Initial qualification. An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers.

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment, counseling, and identification of contraindications to the vaccine;
9. Immunization record management; and

10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. Continuing education. During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of continuing education related to vaccines.

8.33(3) *Protocol requirements.* A pharmacist may administer vaccines pursuant to CDC protocols. A protocol shall be unique to a pharmacy and shall identify all pharmacists authorized to administer vaccines pursuant to the protocol. Links to CDC protocols shall be provided on the board's Web site at www.iowa.gov/ibpe. A protocol:

a. Shall be signed by a licensed Iowa prescriber practicing in Iowa.

b. Shall expire no later than one year from the effective date of the signed protocol.

c. Shall be effective for patients who wish to receive a vaccine administered by an authorized pharmacist, who meet the CDC recommended criteria, and who have no contraindications as published by the CDC.

d. Shall require the authorized pharmacist to notify the prescriber who signed the protocol within 24 hours of a serious complication and shall submit a Vaccine Advisory Event Reporting System (VAERS) report.

8.33(4) *Influenza and other emergency vaccines.* An authorized pharmacist shall only administer via protocol, to patients six years of age and older, influenza vaccines and other emergency vaccines in response to a public health emergency.

8.33(5) *Other adult vaccines.* An authorized pharmacist shall only administer via protocol, to patients 18 years of age and older, the following vaccines:

a. A vaccine on the ACIP-approved adult vaccination schedule.

b. A vaccine recommended by the CDC for international travel.

8.33(6) *Vaccines administered via prescription.* An authorized pharmacist may administer any vaccine pursuant to a prescription or medication order for an individual patient. In case of serious complications, the authorized pharmacist shall notify the prescriber who authorized the prescription within 24 hours and shall submit a VAERS report.

8.33(7) *Verification and reporting.* The requirements of this subrule do not apply to influenza and other emergency vaccines administered via protocol pursuant to subrule 8.33(4). An authorized pharmacist shall:

a. Prior to administering a vaccine identified in subrule 8.33(5) or subrule 8.33(6), consult the statewide immunization registry or health information network.

b. Within 30 days following administration of a vaccine identified in subrule 8.33(5) or subrule 8.33(6), report the vaccine administration to the statewide immunization registry or health information network and to the patient's primary health care provider, if known.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 9/18/13.